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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,531	09/10/2003	Hong Gao	WYNC-0329 / AM101205(NP)	4794
23377	7590	10/25/2004	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103			HABTE, KAHSA Y	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,531

Applicant(s)

GAO ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-24 and 28 is/are allowed.
- 6) ☒ Claim(s) 25 is/are rejected.
- 7) ☒ Claim(s) 26-27 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/9/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-28 are pending.

Information Disclosure Statement

2. The information disclosure statement filed 2/9/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed.

The examiner did not consider the references that are not submitted with the case. Applicants have to provide the references listed in 3, 5, 7, 9-10, 14 and 17 of the form. Applicants indicate that the references listed in 3, 5, 7, 9-10, 14 and 17 are "too voluminous" and will not be forwarded to the US Patent and believe that they are obtainable by the Examiner. If applicants want the references to be considered, they have to provide relevant pages from the "voluminous" references. In regard to WO 94/01437 (see 20 on page 3 of the IDS), the reference is not considered because there is no copy. Applicants indicate that said WIPO document is cited in PCT /US03/28469, but this argument is not relevant. Applicants have to provide said WIPO document if so that the examiner consider the reference.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment many of the diseases recited in claim 25, does not reasonably provide enablement for the treatment of sexual dysfunction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There has been recited a method of treating eating disorders and sexual dysfunction, but the specification is not enabled for such a scope.

Scope of sexual dysfunction is very broad. It includes infertility and sexual transmitted diseases. Infertility can be caused by any interruption in the usual process of fertilization, pregnancy, and birth, which includes ejaculation of normal amounts of healthy sperm, passage of the sperm through the cervix and into the fallopian tube of the female, passage of an ovum (egg) down the fallopian tube from an ovary, fertilization in the fallopian tube, implantation of the fertilized egg in a receptive uterus, and the ability to carry the fetus to term. In women, the most common problems are failure to ovulate and blockage of the fallopian tubes. In men, low sperm count is the most common problem. Note that some of these are hormonal, others can be physical problems in the body.

Sexually transmitted disease (STD) or venereal disease, term for infections acquired mainly through sexual contact. Five diseases were traditionally known as venereal diseases: gonorrhea, syphilis, and the less common granuloma inguinale,

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lymphogranuloma venereum, and chancroid. In the 1960s up to 20 other diseases were recognized as being transmitted by sexual contact, and the term “sexually transmitted disease” came into use. Some of the more common of these are AIDS, genital herpes (see herpes simplex), chlamydia, and human papillomavirus. Other diseases or infestations that can be transmitted sexually include giardiasis, amebiasis, scabies, pubic “crab” lice (see louse), hepatitis (A, B, and C), group B streptococcal infections (see streptococcus), cytomegalovirus infection, and the protozoan infection trichomoniasis.

STDs are generally graver in women, in whom diagnosis is often more difficult and treatment less available than for men; untreated they can lead to infertility or cause miscarriage, premature birth, or infection of the newborn. In some instances two or more infections may be present concurrently. Other STDs are often seen in tandem with AIDS, partly because open sores that they produce can provide an easy route for the AIDS virus to enter the body.

Granuloma inguinale is caused by *Calymmatobacterium granulomatis* and is common in tropical and subtropical regions. Early lesions appear as painless, red, open sores on the skin of the genital and pelvic regions, succeeded by a spreading ulceration of the tissues. If not treated, the condition becomes chronic and may lead to death through anemia and general debility. Antibiotics such as tetracycline can eliminate the infection.

Lymphogranuloma venereum, also common in tropical and subtropical regions, is caused by a strain of *Chlamydia trachomatis*, an organism classified as a bacterium but

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having some viral characteristics. The primary genital lesion is often overlooked. The lymphatic structures about the pelvic and rectal region then become involved; blockage of such structures may cause disfigurement and scarring of external genitals. Fever and headache are other constitutional symptoms. Severe involvement of the rectal mucosa may cause intestinal obstruction or stricture. Tetracycline is the drug of choice, although other antibiotics are effective.

Chancroid is an acute localized infection caused by a bacterium called *Hemophilus ducreyi*. It can result in painful ulcerations of the skin, usually in the groin. In women symptoms may be absent or limited to painful urination, defecation, or intercourse. Involvement of the lymph nodes occurs in more than half the cases.

Sexual dysfunction can be the result of psychological problems such as depression and anxiety. Since sexual dysfunction is very broad and differs greatly between males and females, the enablement rejection is proper.

Objection

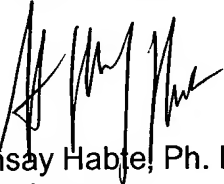
4. Claims 26-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

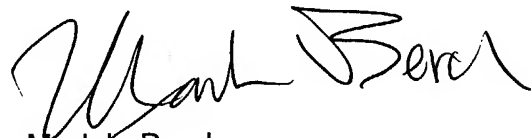
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Habte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
October 21, 2004